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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,156	04/20/2006	Tetsushi Taguchi	052075	2620

38834 7590 04/23/2009

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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,156	TAGUCHI ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment after Non-final rejection filed on December 31, 2008 is acknowledged. Claims 1-6 are pending in this application. Applicant elected species alkali-solubilized collagen for biodegradable polymer, DMSO for the organic solvent, tri-carboxylic acid for different hardening component, succinimidyl for the "different hardening component, soft and soft tissue for types of tissue, and hemostatic from intravascular material in the reply filed on June 18, 2008. Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, and the election had been treated as an election without traverse. The restriction was deemed proper and made FINAL in the previous office action. Claims 1-6 are examined on the merits in this office action.

Terminal Disclaimer

1. The terminal disclaimer filed on December 31, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application 10/527,694 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Withdrawn Objections and Rejections

2. Objection of claim 2, as being improper dependent form for failing to further limit the subject matter of a previous claim, is hereby withdrawn in view of Applicant's amendment to the claim.

3. Rejection of claim 1 under 35 U.S.C. 112, second paragraph, is hereby withdrawn in view of Applicant's amendment. However, a revised rejection follows below, due to the amendment.

4. Rejection of claims 1-6 under 35 U.S.C. 102(b), as being anticipated by Linden et al (US Patent No. 5,634,936), is hereby withdrawn in view of Applicant's arguments and amendment to the claims.

5. Provisional Obviousness Double patenting rejection of claims 1-5 are hereby withdrawn in view of Applicant's filing of Terminal Disclaimer.

Maintained and Revised Rejection

35 U.S.C. 112, 2nd

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 recites, "…a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is modified with an electron-attracting group." It is unclear what derivatives of di- or tri-carboxylic acid of the citric acid cycle is encompassed within a derivative. The specification does not fully define what a derivative of di- or tri-carboxylic acid of the citric acid cycle is encompassed of. The specification discloses that "a di- or

tri-carboxylic acid of the citric acid cycle to be used in the present invention may be malic acid, oxalacetic acid, citric acid, cis-asconitic acid, 2-ketoglutaric acid, or derivatives thereof" (see paragraph [0018] of instant specification 2006/0239958 A1). Because claims 2-6 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

9. Claim 2 recites, "electron-attracting group, and derivatives thereof." It is unclear what compounds are encompassed within the derivatives of electron-attracting groups. The specification does not fully define what is encompassed within derivatives of electron-attracting groups. For example, it is unclear what modifications would be considered to be encompassed within derivatives of electron-attracting groups. The dictionary defines a derivative as "A chemical substance derived from another substance either directly or by modification or partial substitution" (see p. 3 of definition, enclosed).

35 U.S.C. 112, 1st

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the

filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of

certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a two-component, bio-degradable/absorbable adhesive medical material comprising a bonding component composed of a solution containing a biodegradable polymer and a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is modified with an electron attracting-group and derivatives of electron-attracting group. The generic statements a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is modified with an electron-attracting group, and derivatives thereof do not provide ample written

description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claims 1 and 2 are broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that has a positive charge and function as an electron-attracting group, and make up the derivatives of electron-attracting group and derivatives of di or tri-carboxylic acid, and any other small compounds, organic compounds that can function as an electron-attracting group. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives, variance and homologs. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a di- or tri-carboxylic acid

derivative, electron-attracting group, and derivatives of electron-attracting group, and other synthetic peptide or peptide-like molecule and peptidomimetics or amino acid mimetics that can function as an electron-attracting group or derivatives of di- or tri-carboxylic acid of citric acid cycle.

The specification discloses that a low-molecular weight derivative is prepared by modifying a carboxyl group in a di- or tri-carboxylic acid of the citric acid cycle, with an electron-attracting group (one or a combination of two or more selected from the group consisting of a succinimidyl group, a sulfosuccinimidyl group, a maleimidyl group, a phthalimidyl group, an imidazolyl group, a nitrophenyl group and a tresyl group, and derivatives thereof) (see abstract and paragraph [0019]). Further, the specification discloses that "a biological low-molecular-weight derivative to be used in the present invention is prepared by introducing an active ester into the di- or tri-carboxylic acid of the citric acid cycle through the reaction between the di- or tri-carboxylic acid, and an electron-attracting group (see paragraph [0019] of instant specification US 2006/0239958 A1)…low-molecular-weight derivative may be obtained by adding a molecule serving as an electron-attracting group to an organic solvent solution of the di- or tri-carboxylic acid of the citric acid cycle, under the presence of a condensing agent, such as 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide, and purifying an obtained product by silica-gel column chromatography (see paragraph [0020]). The working example only describes the citric acid derivative (CAD) as the biological low-molecular-weight derivative (see paragraph [0029] and Inventive Examples 1-4). The examples show that three carboxyl groups of a citric acid were modified with N-

hydroxysuccinimide. The specification discloses comparative examples (Examples 1-3) where BERIPLAST P®, GRF-GLUE®, and DERMABOND® were used to compare the bonding strength of each biological tissue adhesive (see paragraphs [0034]-[0038]). The specification discloses that "as seen in Table 2, while the biological tissue adhesive in Inventive Example 4 using CAD is inferior to Comparative Example 3, it has a higher bonding strength than those of the biological tissue adhesives in Comparative Examples 1 and 2" (see Table 2). The specification does not describe the structures of CADs. An election-attracting group can be any compound having a positive charge, and functions as an electron acceptor. Any peptide, protein, organic molecules that are biologically active can be an election-acceptor. Description of citric acid derivative is not sufficient to encompass numerous other peptides, proteins and other biologically active molecules that belong to the same genus. For example, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the genus. For example, if the derivative of a di- or tri-carboxylic acid of the citric cycle has a modification with an election-attracting group, then this derivative can be anything having a positively charged compound. If the positively charged compound is a protein having 30 amino acid residues, this implies that there are $30^{20} = 3.49 \text{ X } 10^{29}$ different sequence possibilities, since there are 20 naturally occurring amino acids. When the non-natural amino acids (such as D-isomers, b-amino acids, g-amino acids, e-amino acids, and protected amino acids) are factored into the equation, there are innumerable numbers of possibilities for the di- or tri-carboxylic acid derivatives. There is not

sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Response to Applicant's Arguments

12. Applicant argues that "claim 1 has been amended for clarification to recite 'a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is modified with an electron-withdrawing group'". Applicant argues that "the subject matter claimed in claims 1-6 are sufficiently described in the specification."

13. Applicant's arguments have been fully considered but have not been found persuasive. An electron-attracting (withdrawing or accepting) group can be any compound that has a positive charge. These electron-attracting group, therefore, can be any peptide, protein, small molecule, organic molecule, amino mimetic, peptidomimetic

and so on that have positive charges, and function as an electron-acceptor. The specification discloses that "the electron-withdrawing group may be one or a combination of two or more selected from the group consisting of a succinimidyl group, a sulfosuccinimidyl group, a maleimidyl group, a phthalimidyl group, an imidazolyl group, a nitrophenyl group, and tresyl group, and derivatives thereof. The specification does not disclose other compounds that functions as electron-withdrawing group. Furthermore, the specification does not describe what is encompassed within derivatives of these electron-attracting groups. As defined by http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=derivative, a derivative is a chemical substance derived from another substance either directly or by modification or partial substitution. Therefore, a derivative of electron-withdrawing group of succinimidyl group may be any compound derived from succinimidyl compound. Furthermore, as described in the body of the rejection, a protein, a peptide having a positive charge can function as an election-attracting group. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

35 U.S.C. 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

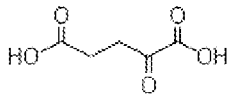
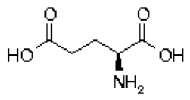
15. Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuda et al (JP 09-103479, as filed with IDS; translated version enclosed of the full document).

16. Matsuda et al teach a less toxic crosslinking method and a medical material formed by this method. The medical material is formed by crosslinking gelatin by succinimidized poly-L-glutamic acid. Matsuda teaches the method of mixing an aqueous solution containing the gelatin and an aqueous solution containing the succinimidized poly-L-glutamic acid and crosslinking the gelatin and the succinimidized poly-L-glutamic acid. Furthermore, the material is a medical material, such as vital adhesive, hemostatic material, embolous material for blood vessel and sealant of aneurysm which is used by direct crosslinking on medical treatment site (see abstract). The working example 1 discloses the method of making the gelling reaction with Poly-L-glutamic acid and gelatin in buffer solution (see paragraph [0006]) and the n-hydroxysuccinimide, poly-L-glutamic acid and a 1-ethyl 3-(3-dimethylaminopropyl) carbodiimide hydrochloride (EDC) were mixed and melted in DMSO. Since claim 1 recites, “a bonding component consisting of a solution containing a biodegradable polymer and either one of an organic solvent, water and a mixture of water and an organic solvent…”, and buffer solution comprises of water and salts, this meets the limitation of claims 1-3 and 5-6. Please note, the intended use of claim 5 has not been given any patentable weight, since they do not further limit the compound.

Response to Applicant's Arguments

17. Applicant argues that "poly-L-glutamic acid is not a di- or tri-carboxylic acid of the citric acid cycle. In contrast, di- or tri-carboxylic acid of the citric acid cycle is used in the present invention such as malic acid, oxalacetic acid, citric acid, cis-aconitic acid, 2-ketoglutaric acid." Applicant further argues that "Matsuda et al does not teach or suggest, among other things, 'a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is chemically modified with an electron-attracting group."

18. Applicant's arguments have been fully considered but have not been found persuasive. Matsuda teaches succinimized poly-L-glutamic acid and crosslinking the gelating and the succinimidized poly-L-glutamic acid. The instant specification discloses that "a di- or tri-carboxylic acid of the citric acid cycle to be used in the present invention may be malic acid, oxalacetic acid, citric acid, cis-asconitic acid, 2-ketoglutaric acid, or derivatives thereof" (see paragraph [0018] of instant specification 2006/0239958 A1).

The structure of 2-ketoglutaric acid is  (see http://chemblink.com/products/328-50-7.htm). A structure of L-glutamic acid is  . L-glutamic acid is a derivative of 2-ketoglutaric acid. The dictionary defines a derivative as "A chemical substance derived from another substance either directly or by modification or partial substitution" (see p. 3 of definition, enclosed). Therefore, L-glutamic acid is a derivative of 2-ketoglutaric acid, meeting the limitation of

di- or tri-carboxylic acid derivative. Furthermore, Matsuda teaches succinimidized poly-L-glutamic acid, which reads on the electron-attracting group (succinimidyl group), and the hardening component (di- or tri-carboxylic acid derivative). Therefore, the Matsuda reference teaches all of the active ingredients and components claimed in the instant claims. Matsuda reference anticipates instant claims 1-3 and 5-6.

New Rejection

35 U.S.C. 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda et al (JP 09-103479) in view of Linden et al (US Patent No. 5,634,936).

22. Matsuda et al teach a less toxic crosslinking method and a medical material formed by this method. The medical material is formed by crosslinking gelatin by succinimidized poly-L-glutamic acid. Matsuda teaches the method of mixing an aqueous solution containing the gelatin and an aqueous solution containing the succinimidized poly-L-glutamic acid and crosslinking the gelatin and the succinimidized poly-L-glutamic acid. Furthermore, the material is a medical material, such as vital adhesive, hemostatic material, embolous material for blood vessel and sealant of aneurysm which is used by direct crosslinking on medical treatment site (see abstract). The working example 1 discloses the method of making the gelling reaction with Poly-L-glutamic acid and gelatin in buffer solution (see paragraph [0006]) and the n-hydroxysuccinimide, poly-L-glutamic acid and a 1-ethyl 3-(3-dimethylaminopropyl) carbodiimide hydrochloride (EDC) were mixed and melted in DMSO. Since claim 1 recites, “a bonding component consisting of a solution containing a biodegradable polymer and either one of an organic solvent, water and a mixture of water and an organic solvent…”, and buffer solution comprises of water and salts, this meets the limitation of claims 1-3 and 5-6. Please note, the intended use of claim 5 has not been given any patentable weight, since they do not further limit the compound. The reference discloses DMSO. However, the difference between the reference and the instant claim is that the reference does not teach combination of water and organic solvent.

23. However, Linden teaches a device for closing off a septal defect including a polymeric self-hardening material in a specific conformation which is delivered directly to a cardiac tissue or into a balloon which spans both surfaces of the defect, and hardened in-situ by change in pH or ionic concentration, organic solvents (see abstract). Linden teaches biodegradable polymer that are collagen or poly-L-lysine which precipitates above a pH of 3.0. Linden teaches that polymers such as low molecular weight poly-L-lactic acid are soluble in DMSO and would precipitate on replacing the water miscible DMSO with water or saline solutions (see column 6, lines 46-51). Linden further claims an apparatus for closing off a septal defect (see claims), a plug that meets the limitation of a sealant or blood vessel embolizing material.

24. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Matsuda et al and Linden et al, since they both teach a medical material for hemostatic material, blood-vessel embolizing material, a sealant and an aneurysm closing material. One of ordinary skill in the art would have been motivated to combine, since Linden teaches that low molecular weight polymers, such as poly-L-lactic acid are soluble in DMSO and would precipitate on replacing the water miscible DMSO with water or saline solutions, thus combining DMSO and water would precipitate the low molecular weight polymers, such as poly-L-lactic acid and poly-L-glutamic acid. There is a reasonable expectation of success, since Linden teaches that poly-L-lactic acid was successful, poly-L-glutamic acid would also be successful.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). No claim is allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654